UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/720,765	11/24/2003	James Martucci	EIS-5799 DIV.1	4921

29200 7590 07/25/2007

BAXTER HEALTHCARE CORPORATION
1 BAXTER PARKWAY
DF2-2E
DEERFIELD, IL 60015

EXAMINER	
MORGAN, ROBERT W	

ART UNIT	PAPER NUMBER
3626	

MAIL DATE	DELIVERY MODE
07/25/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/720,765	MARTUCCI ET AL.	
	Examiner	Art Unit	
	Robert W. Morgan	3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-6 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-6 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Notice to Applicant

1. This communication is in response to the amendment filed 5/17/07. Claim 6 has been amended. Claims 1-6 are presented for examination.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

3. Claims 1-6 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,671,763 to Engelson et al.

As per claim 1, Engelson et al. teaches a method for medication delivery comprising the steps of:

(a) providing a medication container containing a prescribed medication and a first label containing data on the prescribed medication and instruction of delivering of the medication, the

prescribed medication data and the instruction of delivering the medication being provided in machine readable format is met by the order transmitted to the institution's pharmacy which is processed and generally includes the patient's name, the drug name, and the appropriate treatment parameters are represented on the label (182, Fig. 5) affixed to container (see: column 13, lines 3-21);

(b) providing a tag adapted to be worn by a patient, the tag having a second label containing data of the patient, the patient data being provided in machine readable format (see: column 7, lines 48-51 and Fig. 5A);

(c) providing a handheld computing device (In another embodiment, the care management system is a portable computer (235, Fig. 15) carried with physicians, nurses or technicians as they circulate through the institution (see: column 15, lines 35-50)) with:

means for reading the prescribed medication data and medication delivery instruction from the first label and patient data from the second label is met by barcodes (182, Fig. 5) and (175, 5A) being read by barcode reader (68, Fig. 2) (see: column 7, lines 48-54 and column 8, lines 12-19);

means for storing the data and instruction (46, Fig 2) (see: column 19-24);

means for communicating data and instruction to other electronic devices is met by the file server that includes communication hardware for communicating with the hospital network (see: column 5, lines 25-32);

(d) the handheld computing device reading the prescribed medication data and medication delivery instruction from the first label is met by the barcode (182, Fig. 5) being read by a barcode reader (see: column 8, lines 12-19);

(e) the handheld computing device reading the patient data from the second label is met by the care management system (30, Fig. 2) reading barcode (182, Fig. 5) and patient bracelet (170, Fig. 5A) using a barcode reader to ensure that the right drug is delivered to the right patient at the right time in the right manner (see: column 8, lines 12-19); and

(f) the handheld computing device comparing the prescribed medication data to the patient data and confirming a match between the prescribed medication data and the patient data is met by the care management system (30, Fig. 2) reading barcode (182, Fig. 5) and patient bracelet (170, Fig. 5A) using a barcode reader to ensure that the right drug is delivered to the right patient at the right time in the right manner (see: column 8, lines 12-19).

As per claim 2, Engelson et al. teaches the claimed step of the handheld computing device communicating and downloading the medication delivery instruction to a medication delivery device to deliver the medication to the patient. This limitation is met when medication is to be delivered using an infusion pump the care management system automatically downloads information consisting of the appropriate configuration (see: column 14, lines 3-13). In another embodiment, the care management system is a portable computer (235, Fig. 15) carried with physicians, nurses or technicians as they circulate through the institution (see: column 15, lines 35-50).

As per claim 3, Engelson et al. teaches the claimed step of the medication delivery device performing periodic checks of the operating parameters of the medication delivery device against the medication delivery instruction downloaded from the handheld computing device to ensure the operating parameters are within the ranges set by the medication delivery instruction after starting the delivery of the medication. This feature is met by the medical administrative

management module (110, Fig. 3) that automatically records the start time of the infusion, queries the pump periodically throughout the infusion and maintains a continuous log of the infusion and the volume infused in a patient MAR (see: column 8, lines 41-47).

As per claim 4, Engelson et al. teaches the claimed the first label is encoded with the prescribed medication data and the instruction of delivering the medication derived from a print stream generated from a pharmacy information system. This limitation is met by the order transmitted to the institution's pharmacy which is processed and generally includes the patient's name, the drug name, and the appropriate treatment parameters are represented on the label (182, Fig. 5) affixed to container (see: column 13, lines 3-21).

As per claim 5, Engelson et al. teaches a method for medication delivery comprising the steps of:

(a) providing a medication container containing a prescribed medication and a first label containing data on the prescribed medication and instruction of delivering of the medication, the prescribed medication data and the instruction of delivering the medication being provided in machine readable format is met by the order transmitted to the institution's pharmacy which is processed and generally includes the patient's name, the drug name, and the appropriate treatment parameters are represented on the label (182, Fig. 5) affixed to container (see: column 13, lines 3-21);

(b) providing a tag adapted to be worn by a patient, the tag having a second label containing data of the patient, the patient data being provided in machine readable format (see: column 7, lines 48-51 and Fig. 5A);

(c) providing a handheld computing device (In another embodiment, the care management system is a portable computer (235, Fig. 15) carried with physicians, nurses or technicians as they circulate through the institution (see: column 15, lines 35-50)) with:

means for reading the prescribed medication data and medication delivery instruction from the first label and patient data from the second label is met by barcodes (182, Fig. 5) and (175, 5A) being read by barcode reader (68, Fig. 2) (see: column 7, lines 48-54 and column 8, lines 12-19);

means for storing the data and instruction is met by (46, Fig 2) (see: column 19-24);

means for communicating data and instruction to other electronic devices is met by the file server that includes communication hardware for communicating with the hospital network (see: column 5, lines 25-32);

(d) the handheld computing device reading the prescribed medication data and medication delivery instruction from the first label is met by the barcode (182, Fig. 5) being read by a barcode reader (see: column 8, lines 12-19);

(e) the handheld computing device reading the patient data from the second label is met by the care management system (30, Fig. 2) reading barcode (182, Fig. 5) and patient bracelet (170, Fig. 5A) using a barcode reader to ensure that the right drug is delivered to the right patient at the right time in the right manner (see: column 8, lines 12-19);

(f) the handheld computing device comparing the prescribed medication data to the patient data and confirming a match between the prescribed medication data and the patient data is met by the care management system (30, Fig. 2) reading barcode (182, Fig. 5) and patient

bracelet (170, Fig. 5A) using a barcode reader to ensure that the right drug is delivered to the right patient at the right time in the right manner (see: column 8, lines 12-19); and

(g) the handheld computing device communicating and downloading the medication delivery instruction to a medication delivery device to deliver the medication to the patient is met when medication is to be delivered using an infusion pump the care management system automatically downloads information consisting of the appropriate configuration (see: column 14, lines 3-13).

As per claim 6, Engelson et al. teaches a method for medication delivery comprising the steps of:

(a) identifying medication data contained in a first label on a medication container containing a prescribed medication, the first label containing data on the prescribed medication and instruction of delivering of the medication, the prescribed medication data and the instruction of delivering the medication being provided in machine readable format is met by the order transmitted to the institution's pharmacy which is processed and generally includes the patient's name, the drug name, and the appropriate treatment parameters are represented on the label (182, Fig. 5) affixed to container (see: column 13, lines 3-21);

(b) identifying patient data contained in a second label on a tag adapted to be worn by a patient, the second label containing data of the patient, the patient data being provided in machine readable format (see: column 7, lines 48-51 and Fig. 5A);

(c) comparing the medication data to the patient data by a handheld computing device wherein the handheld computing device is met by the care management system (30, Fig. 2) reading barcode (182, Fig. 5) and patient bracelet (170, Fig. 5A) using a barcode reader to ensure

that the right drug is delivered to the right patient at the right time in the right manner (see: column 8, lines 12-19):

means for reading the prescribed medication data and medication delivery instruction from the first label is met by barcodes (182, Fig. 5) and (175, Fig. 5A) being read by barcode reader (68, Fig. 2) (see: column 7, lines 48-54 and column 8, lines 12-19);

means for storing the data and instruction is met by (46, Fig 2) (see: column 19-24); and

means for communicating data and instruction to other electronic devices is met by the file server that includes communication hardware for communicating with the hospital network (see: column 5, lines 25-32);

(d) the handheld computing device confirming the data and downloading the instruction of delivering the medication to a medication delivery device is met when medication is to be delivered using an infusion pump the care management system automatically downloads information consisting of the appropriate configuration (see: column 14, lines 3-13).

Response to Arguments

4. Applicant's arguments filed 5/17/07 have been fully considered but they are not persuasive. Applicant's arguments will be addressed hereinbelow in the order in which they appear in the response filed 5/17/07.

(A) At pages 5-7 of the 5/17/07 response, Applicants argues in substance that Engelson does not include means for reading the prescribed medication data and medication delivery instruction from the first label and patient data from the second label and does not teach or suggest that the handheld computing device reads the prescribed medication data and medication delivery instruction from the first label, and that the handheld computing device reads the patient

data from the second label. The Examiner respectfully submits that Engelson teaches care management system (30, Fig. 1) that includes attached to the pharmacy CPU, a bar code reader (68, Fig. 1) which is adapted to read barcode labels that may be attached to drug containers, equipment, or caregiver identification badges (see: column 5, lines 44-48). In addition, Engelson teaches a barcode (182, Fig. 5) being read by a barcode reader (see: column 8, lines 12-19). Furthermore, in another embodiment, the care management system can be a portable computer (235, Fig. 15) carried with physicians, nurses or technicians as they circulate through the institution (see: column 15, lines 35-50). The clearly indicates that the system can be portable and include a means for reading bar codes such as bar code reader.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert W. Morgan whose telephone number is (571) 272-6773. The examiner can normally be reached on 8:30 a.m. - 5:00 p.m. Mon - Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on (571) 272-6776. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Robert Morgan
Robert Morgan
Primary Examiner
Art Unit 3626